

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0516; FRL-9972-36]

Rimsulfuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances, including tolerances with regional registration, for residues of rimsulfuron in or on multiple commodities that are identified and discussed later in this document. In addition, this regulation removes several previously established tolerances that are superseded by this final rule. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [insert date of publication in the **Federal Register**]. Objections and requests for hearings must be received on or before [insert date 60 days after date of publication in the **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0516, is available at *http://www.regulations.gov* or at the

Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

• Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0516 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [insert date 60 days after date of publication in the **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA

without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0516, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC),
 (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of Thursday, March 23, 2017 (82 FR 14846) (FRL-9957-99), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8496) by IR-4 Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.478 be amended by establishing tolerances for residues of the herbicide rimsulfuron, N-[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide, in or on Berry,

low growing, except strawberry, subgroup 13-07H at 0.01 parts per million (ppm); Fruit, citrus, group 10-10 at 0.01 ppm; Fruit, pome, group 11-10 at 0.01 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.01 ppm; Fruit, stone, group 12-12 at 0.01 ppm; Nut, tree, group 14-12 at 0.01 ppm; Vegetable, tuberous and corm, subgroup 1C at 0.1 ppm; and tolerances with regional restrictions in or on Fescue, forage at 0.01 ppm; Fescue, hay at 0.01 ppm; Ryegrass, perennial, forage at 0.01 ppm; and Ryegrass, perennial, hay at 0.01 ppm. That document referenced a summary of the petition prepared by E. I. du Pont de Nemours and Company, the registrant, which is available in the docket, http://www.regulations.gov. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerance levels that vary from what the petition requested. The reason for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children

to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for rimsulfuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with rimsulfuron follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicity database indicates that target organs for rimsulfuron are the liver and kidney in the rat and dog, along with the testis and blood in the mouse and dog. In the mouse, the stomach was also a target organ.

Adverse changes in body weight and food consumption were observed in rats, mice and dogs. In subchronic and chronic toxicity studies in rats, toxic effects included decreased body weight, decreased body weight gain, increased relative liver and absolute kidney weights, and diuresis. In the subchronic study in mice, increased red blood cell

and hemoglobin, and decreased body weight gain and food efficiency were observed. In the chronic study in mice, decreased body weight, increased incidences of dilation and cysts in the glandular stomach, and degeneration of the testicular artery and tunica albuginea were observed. In the subchronic study in dogs, diuresis was indicated by urinary volume, platelet concentration and kidney weights accompanied by decreased urinary osmolality. In the chronic study in dogs, increased absolute liver and kidney weights, increased seminiferous tubule degeneration, and increased number of spermatid giant cells present in epididymides in males were observed.

In the developmental toxicity study in rats, no toxicity was seen at the highest dose tested (HDT). In the developmental toxicity study in rabbits, and in the 2-generation reproduction toxicity study in rats, developmental/offspring toxicity was seen in the presence of maternal/systemic toxicity and at similar dose levels. There is no quantitative or qualitative evidence of increased susceptibility following pre- and/or post-natal exposures in the developmental and reproduction studies.

There is no indication in the database that rimsulfuron is neurotoxic or immunotoxic. Rimsulfuron is not mutagenic and has been classified as "not likely to be carcinogenic to humans," based on the lack of evidence for carcinogenicity in studies conducted in rats and mice.

Specific information on the studies received and the nature of the adverse effects caused by rimsulfuron as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://www.regulations.gov in document entitled, "SUBJECT: Rimsulfuron. Human

Health Risk Assessment in Support of a Petition (PP#6E8496) for the Establishment of Permanent Tolerances on Tuberous and Corm Vegetable Subgroup 1C, Small Vine Climbing Fruit Except Fuzzy Kiwifruit Subgroup 13-07F, Low Growing Berry Except Strawberry Subgroup 13-07H, Tolerances with Regional Registrations for Ryegrass and Fescue and Crop Group Conversions for Citrus Fruit Group 10-10, Pome Fruit Group 11-10, Stone Fruit Group 12-12, and Tree Nut Group 14-12," dated May 5, 2017 at pp. 31-34 in docket ID number EPA-HQ-OPP-2016-0516.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete

description of the risk assessment process, see http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.

A summary of the toxicological endpoints for rimsulfuron used for human risk assessment is shown in Table 1 of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for Rimsulfuron for Use in Human Health Risk Assessment

| | | T | | |
|---------------------|---|--------------------|---------------------------|--|
| Exposure/Scenario | Point of Departure and | RfD, PAD, | Study and | |
| | Uncertainty/Safety | LOC for Risk | Toxicological Effects | |
| | Factors | Assessment | | |
| | | | | |
| Acute Dietary (All | An endpoint attributable | e to a single dose | was not identified in the | |
| populations) | database. | | | |
| | | | | |
| Chronic dietary | NOAEL= 11.8 | Chronic RfD = | Combined Chronic/ | |
| (All populations) | mg/kg/day | 0.118 | Carcinogenicity – Rat | |
| | $UF_A = 10x$ | mg/kg/day | LOAEL = 121 | |
| | $UF_H = 10x$ | | mg/kg/day based on | |
| | FORA GE 1 | cPAD = 0.118 | decreased body weight | |
| | FQPA SF = 1x | mg/kg/day | gains and liver effects. | |
| | | | | |
| Cancer (Oral, | Rimsulfuron is considered "not likely to be carcinogenic to | | | |
| dermal, inhalation) | humans" due to the absence of tumors in the available rat and | | | |
| | mouse carcinogenicity studies. | | | |

FQPA SF = Food Quality Protection Act Safety Factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, LOC = level of concern, UF_A = extrapolation from animal to human (interspecies), UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

- 1. Dietary exposure from food and feed uses. In evaluating dietary exposure to rimsulfuron, EPA considered exposure under the petitioned-for tolerances as well as all existing rimsulfuron tolerances in 40 CFR 180.478. EPA assessed dietary exposures from rimsulfuron in food as follows:
- i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for rimsulfuron; therefore, a quantitative acute dietary exposure assessment is unnecessary.
- ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed that rimsulfuron residues were present at tolerance levels in all commodities for which

tolerances have been established and currently proposed, and 100 percent crop treated (PCT) with rimsulfuron.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that rimsulfuron does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. Anticipated residue and percent crop treated (PCT) information. EPA did not use anticipated residue or PCT information in the dietary assessment for rimsulfuron.

Tolerance level residues and 100 PCT were assumed for all food commodities.

2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for rimsulfuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of rimsulfuron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.

Based on the Pesticides in Flooded Applications Model (PFAM) and the Wisconsin cranberry (worst case) scenario to conduct an assessment of surface water exposure to total toxic residue (TTR) of rimsulfuron (PFAM model was developed specifically for regulatory applications to estimate exposure for pesticides used in flooded agriculture such as rice paddies and cranberry bogs) and Pesticide Root Zone Model Ground Water (PRZM GW) and the Tier I assessment for applications of rimsulfuron to corn in Wisconsin (worst case), the estimated drinking water concentrations (EDWCs) of

rimsulfuron for acute exposures are estimated to be 9.59 parts per billion (ppb) for surface water and 22.2 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 1.70 ppb for surface water and 19.7 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 19.7 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Rimsulfuron is not registered for any specific use patterns that would result in residential exposure.

4. Cumulative effects from substances with a common mechanism of toxicity.

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Rimsulfuron belongs to the class of pesticides known as sulfonylureas (SUs). The SUs share a core chemical structure with varying degrees of structural similarity. In addition, the SUs share a pesticidal mode of action (i.e., the inhibition of acetolactate synthase (ALS)), although the function of ALS in humans is unknown and the relevance of this mode of action (MOA) in humans in unclear. Based on toxicity studies, the SUs

do not share a common toxicological profile; instead the target organs vary among the class and are often unspecific, such as changes in body weight or general effects on the liver. Further dividing the SUs into subclasses based on the urea substituent did not result in a clear association of a target organ with any particular substructure.

Based on the weight of the evidence, considering the lack of common toxicological profile of the SUs, the uncertainty in the human relevance of ALS inhibition, and the lack of mammalian MOA data, a testable hypothesis for a common mechanism of action cannot be identified. Therefore, the Agency concludes that no common mechanism of toxicity exists among these pesticides and a cumulative risk assessment (CRA) approach is not appropriate for this class of pesticides. For further explanation, see "SUBJECT: Sulfonylureas: Screening Analysis of Toxicological Profiles to Consider Whether a Candidate Common Mechanism Group Can Be Established", dated 9/9/2015, found at http://www.regulations.gov in docket ID number EPA-HQ-OPP-2016-0516.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.

D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database

on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

- 2. Prenatal and postnatal sensitivity. In the developmental toxicity study in rats, no developmental toxicity was seen at the highest dose tested. In the developmental toxicity study in rabbits and in the 2-generation reproductive study in rats, developmental and offspring toxicity were seen only in the presence of maternal/systemic toxicity. There is no evidence of quantitative or qualitative increased susceptibility following pre- and/or postnatal exposures to rimsulfuron.
- 3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:
 - i. The toxicity database for rimsulfuron is complete.
- ii. There is no indication that rimsulfuron is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or increased SF to account for neurotoxicity.
- iii. There is no evidence that rimsulfuron results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. No acute toxicological endpoint was identified. The chronic dietary food and drinking water exposure assessment utilizes tolerance-level residues and 100 PCT information for all commodities. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to rimsulfuron in drinking water. These assessments will not underestimate the exposure and risks posed by rimsulfuron.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

- 1. Acute risk. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, rimsulfuron is not expected to pose an acute risk.
- 2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to rimsulfuron from food and water will utilize 1.5 % of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for rimsulfuron. Therefore, the chronic aggregate risk is the same as the chronic dietary risk and not of concern.

- 3. Short- and intermediate-term risks. Short- and intermediate-term aggregate exposures take into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD, no further assessment of short- or intermediate-term risk is necessary.
- 4. Aggregate cancer risk for U.S. population. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, rimsulfuron is not expected to pose a cancer risk to humans.
- 5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to rimsulfuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, DuPont method 15033 using highperformance liquid chromatography/electrospray ionization tandem mass spectrometry (HPLC/ESI-MS/MS), is available for determination of residues of rimsulfuron in petitioned-for commodities.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for residues of rimsulfuron in/on any commodity associated with this action.

C. International Trade Considerations

In this final rule, EPA is establishing a crop subgroup tolerance for subgroup 1C (vegetable, tuberous and corm, subgroup 1C) at 0.10 ppm. This subgroup includes the commodity potato, for which a tolerance is currently set at 0.1 ppm. Setting a new tolerance at 0.10 ppm on potato as part of subgroup 1C has a theoretically trade restrictive effect on the import of potatoes, resulting from rounding to significant figures when quantifying residues of rimsulfuron, compared with the current tolerance of 0.1 ppm.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to promptly publish this action with the WTO. Although he subgroup 1C tolerance is being established at 0.10 ppm and is unlikely to impact trade, EPA is establishing an expiration date for the existing potato tolerance following publication of this rule in order to provide a six-month reasonable interval for producers in exporting countries to adapt the modified tolerance. Before that date, residues of rimsulfuron on potato will be permitted under the current tolerance of 0.1 ppm; after that date, residues will need to be in compliance with the new 0.10 ppm subgroup 1C tolerance level.

The tolerance level is appropriate based on available data and residues levels resulting from registered use patterns. The tolerance level for all subgroup 1C commodities is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. None of the other tolerance actions taken in this rulemaking restrict permissible pesticide residues below currently allowed levels in the United States.

Any commodities listed in the regulatory text of this document that are treated with the pesticides subject to this final rule, and that are in the channels of trade following the tolerance revocation, shall be subject to FFDCA section 408(1)(5), as established by FQPA. Under this unit, any residues of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

- 1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA.
- 2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance. Evidence to show that food was lawfully treated may include records that verify the dates that the pesticide was applied to such food.

D. Revisions to Petitioned-For Tolerances

EPA is establishing the tolerance level for "Berry, low growing, except strawberry, subgroup 13-07H" at 0.02 ppm, instead of 0.01 ppm as requested, to fully account for residue loss in the field trial samples during freezer storage from the time of harvest to the time of analysis. Concurrent storage stability samples indicate that as much as half of the residue present in the samples may have been lost between the time of harvest and the time of analysis; therefore, 0.02 ppm (twice LOQ) was selected as the appropriate tolerance for subgroup 13-07H. In addition, the tolerance for subgroup 1C is being established as 0.10 ppm rather than 0.1 ppm to conform with the Agency's practice of using two significant figures.

V. Conclusion

Therefore, tolerances are established for residues of rimsulfuron, N-[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide, to be determined by measuring only rimsulfuron, in or on Berry, low growing, except strawberry, subgroup 13-07H at 0.02 ppm; Fruit, citrus, group 10-10 at 0.01 ppm; Fruit, pome, group 11-10 at 0.01 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit,

subgroup 13-07F at 0.01 ppm; Fruit, stone, group 12-12 at 0.01 ppm; Nut, tree, group 14-12 at 0.01 ppm; Vegetable, tuberous and corm, subgroup 1C at 0.10 ppm; and tolerances with regional restriction on Fescue, forage at 0.01 ppm; Fescue, hay at 0.01 ppm; Ryegrass, perennial, forage at 0.01 ppm; and Ryegrass, perennial, hay at 0.01 ppm. In addition, the Agency is removing the existing tolerances for "fruit, citrus, group 10", "fruit, pome, group 11", "fruit, pome, group 12", "grape", "nut, tree, group 14", and "pistachio" since they are superseded by the tolerances being established in this action. Finally, the Agency is establishing a six-month expiration date for the existing "potato" tolerance at 0.1 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001); Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to

Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seg.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

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List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 22, 2018.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

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Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

- 2. In § 180.478:
- i. Remove the entries for "Fruit, citrus group 10"; "Fruit, pome, group 11"; "Fruit, stone, group 12"; "Grape"; "Nut, tree, group 14"; and "Pistachio" from the table in paragraph (a).
- ii. Add alphabetically the entries to the table in paragraph (a) "Berry, low growing, except strawberry, subgroup 13-07H"; "Fruit, citrus, group 10-10"; "Fruit, pome, group 11-10"; "Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F"; "Fruit, stone, group 12-12"; and "Nut, tree, group 14-12".
 - iii. Revise the entry for "Potato" in the table in paragraph (a).
- iv. Add alphabetically the entry to the table in paragraph (a) "Vegetable, tuberous and corm, subgroup 1C".
 - v. Add footnote 1 to the table in paragraph (a).
 - vi. Revise paragraph (c).

The additions and revisions read as follows:

§ 180.478 Rimsulfuron; tolerances for residues.

(a) * * *

| Commodity | | | | | | Parts per million | | |
|-----------------------|-----------|---------|-----------|----------|----------|-------------------|------|------|
| | * | * | * | * | * | * | * | |
| Berry, low growing | g, except | tstrawb | perry, su | ıbgroup | 13-07H | H | | 0.02 |
| | * | * | * | * | * | * | * | |
| Fruit, citrus, group | 10-10 | | | | | | | 0.01 |
| Fruit, pome, group | 11-10 | | | | | | | 0.01 |
| Fruit, small, vine cl | | except | fuzzy l | kiwifrui | t, subgr | roup 13- | ·07F | 0.01 |
| Fruit, stone, group | 12-12 | | | | | | | 0.01 |
| | * | * | * | * | * | * | * | |
| Nut, tree, group 14- | -12 | | | | | | | 0.01 |
| | * | * | * | * | * | * | * | |
| Potato ¹ | | | | | | | | 0.1 |
| | * | * | * | * | * | * | * | |
| Vegetable, tuberous | s and co | rm, sub | group 1 | IC | | | | 0.10 |

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¹ This tolerance expires on August 12, 2018.

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(c) *Tolerances with regional registrations*. Tolerances with regional registrations, as defined in § 180.1(1), are established for residues of the herbicide rimsulfuron, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specific in the following table is to be determined by measuring only rimsulfuron, N-[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide.

| Commodity | Parts per million |
|-----------------------------|-------------------|
| Fescue, forage | 0.01 |
| Fescue, hay | 0.01 |
| Ryegrass, perennial, forage | 0.01 |
| Ryegrass, perennial, hay | 0.01 |
| | |

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